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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/535,260

05/18/2005

Timo Pulli

3501-1097

5730

466

7590

04/14/2009

YOUNG & THOMPSON

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EXAMINER

COOK, LISA V

ART UNIT

PAPER NUMBER

1641

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DELIVERY MODE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/535,260	<b>Applicant(s)</b> PULLI ET AL.	
	<b>Examiner</b> LISA V. COOK	<b>Art Unit</b> 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 28 August 2008 and 08 January 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) 7-17 and 21-25 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-6, 18-20, and 26-33 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

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## **DETAILED ACTION**

### ***Amendment Entry***

1. The amendment filed 8/28/08 is acknowledged. The specification and claims were modified. Currently, claims 1-33 are pending.
2. Claims 7-17 and 21-25 have been withdrawn from consideration. The new amendments necessitated the instant restriction.

### ***Election/Restrictions***

3. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

To have a general inventive concept under PCT rule 13.1, the inventions need to be linked by a special technical feature. The special technical feature that appears to link claims 1-33 is dual antibody reagent pair, wherein one of the antibodies is produced from a recombinant library, and the reagent pair has utility in non-competitive immunoassays. However, such antibody reagent pairs and their utility in assay procedures were disclosed in the prior art. The reference of Self et al. (Clinical Chemistry, Vol.40, No.11, pages 2035-2041, 1994) disclose a dual antibody reagent-pair being applicable in noncompetitive immunometric assay systems. The assay is based on the interaction of a primary antibody with its ligand in order to form new binding sites, recognizable by a second antibody - which then binds to form a detectable complex. See abstract. The antibodies (fragments) are produced by various procedures. See page 2036 – 2<sup>nd</sup> column.

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Although Self et al. are silent with respect to antibody production from a recombinant library, these procedures were well known in the prior art. For example, see the reference to Arai et al. (Protein Engineering, Vol.13, No.5, pages 369-376, 2000).

Accordingly, the technical feature recited in claims 1-33 is not a contribution over the prior art. The groups set forth below are not so linked as to form a single general concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

- A. Group I, claim(s) 1-6 and 32 are drawn to a non-competitive immunoassay for a small analyte employing a reagent pair (A 1<sup>st</sup> first method employing a special technical feature or reagent pair).
- B. Group II, claim(s) 18-20 and 33 are drawn to process of preparing a reagent pair (A 2<sup>nd</sup> method employing a special technical feature).
- C. Group III, claim(s) 26-31 are drawn to an immunoassay comprising a reagent pair comprising SEQ ID NO:5 and/or sequence combinations of SEQ ID NO:1 and 2 or SEQ ID NO:3 and 4. (A 3<sup>rd</sup> method employing a special technical feature).

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4. The inventions listed as Groups **A** through **C** do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Under PCT rules Applicant is entitled to an examination of one of the combination groupings: (1) a product, a method of using said product and a method of producing said product.

The instant claims are directed to multiple special technical feature (antibody constructs) and methods and/or products that utilize either of the special technical features, therein applicant must select one for further prosecution.

5. Group **C** includes sequences identification numbers. With respect to the separate amino acid structures and the nucleic acid structures, they bear distinct structural or biochemical properties having different binding epitopes (Specification references sequence id. Nos. 1-5). **Therefore, each disclosed patentably distinct amino acid sequences and nucleic acid sequence is considered a separate invention.** See Official Gazette 1232 OG 242(116) March 21, 2000. Therein the O.G. notice permits the examiner to examine up to ten sequences per application based on the use of US PTO resources. Resources are now stretched to the limit, such that only one sequence should be searched per application. It is recognized that although the search for the inventions may overlap they are not totally co-extensive, where by the search for one would fully encompass the search for the others.

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6. Because these inventions are distinct for the reasons given above, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and the search required for Group A through C are not totally inclusive, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

7. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement is traversed (37 CFR 1.143).

8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

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9. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO fax center located in Crystal Mall 1. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Group 1641 Fax number is (571) 273-8300, which is able to receive transmissions 24 hours/day, 7 days/week.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lisa V. Cook whose telephone number is (571) 272-0816. The examiner can normally be reached on Monday - Friday from 7:00 AM - 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Shibuya, can be reached on (571) 272-0806.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group TC 1600 whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

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Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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*4/13/09*

/Lisa Cook/  
Primary Examiner